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April 27 , 1998

Dr. Neal Halsey,

Dear Dr. Halsey

I have read your manuscript and as you may be aware the document is full of omissions and statements not consistent with the data. I will just review a few of them. Please note the proper spelling of my name.

1. (PAGE 4) The document fails to state that no consensus was reached by the attendants. When asked to form a consensus the attendees refused. The draft reflects the views of Dr. Halsey and friends. **It is important to include this information.**

The draft further fails to mention that the authors' conflicts of interest. Readers should be informed that the authors are being paid in excess of \$125,000 per year by several major vaccine manufacturers with multi year funding contracts in place. The authors are also actively seeking funds from another major vaccine manufacturer and vaccine manufacturers provide the majority of the institutes' funding.

2. Specific errors etc.

(Page 1) "*Available evidence indicates no contributory role for immunizations of any type in predisposing to type 1 diabetes mellitus*".

This statement is false and misleading. It is not supported by the data and not agreed to by the attendees as discussed above.

(Page 8, paragraph 2) Note spelling of my name: **J. Barthelow Classen**. The accompanying statements are false . I did not study the effect of BCG vaccines on IDDM in **tropical** countries but European countries.

(Page 9). "*There is no evidence in **animals or humans** data to **suggest** that childhood vaccines increase the risk of type 1 diabetes.*"

The statement is false and I presented data from peer reviewed papers to disproving this statement. The CDC admits on their web site that there is some data to suggest vaccines may increase the risk of IDDM and have published data that the Hep B vaccine when given after 2

months is associated with an odds ratio of 1.9 (Pharmacoepidemiology and Drug Safety 6 Supplement 2: S60).

a. My animal paper, published in a peer reviewed journal, clearly states ***“administration of the pertussis vaccine starting at 8 weeks was associated with an increased incidence of diabetes”*** The studies referenced were with mice not rats. The wording in the draft is very poor and misleading. I suggest wording similar to that in the peer reviewed paper.

b. I clearly stated to Dr. Halsey that I did not permit him to include the data from the HiB vaccine study to be included in the article. The interpretation include in the paper is misleading and not consistent with the design of the study as I discussed in detail. The HiB vaccine study which I presented did not include the meningococcal vaccine.

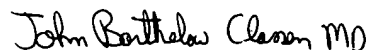
c. (page 10) Dr. De Stefano’s study did not show immunization at birth was associated with a decreased risk of IDDM but instead showed immunization with Hep B starting after 2 months was associated with an increased risk of IDDM, OR=1.9 (Pharmacoepidemiology and Drug Safety 6 Supplement 2: S60).

d. (page 10, #6) Early immunization with DTP and HiB was not a focus of the meeting and therefore should not be part of the paper. To say early immunization is contraindicated is misleading. Several publications have shown early immunization is feasible .

Pediatrics 95(6): 815-822; 1995

J. Pediatrics 128:524-530; 1996

Sincerely,

A handwritten signature in black ink that reads "John Barthelaw Classen MD". The signature is written in a cursive, slightly slanted style.

J. Barthelaw Classen, M.D., M.B.A.